K090601
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510k Summary

MAY 11 2009

A) Submitted by: Schoelly Imaging, Inc.
100 Hartwell St.
West Boylston, MA 01583
Registration: 3005305991

Contact: MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721
F. David Rothkopf
508-231-8842 x20
508-231-8861 Fax

B) Device Name: FSC 2

Common Name: Endoscope and accessories

Device Class: 21 CFR 876.1500 Class II

Product Code: XXX, LED light source
FCW, Light Source, Fiberoptic

Common Name: Surgical camera and accessories

Device Class: 21 CFR 878.4160, Class I, exempt

Product Code FWF

C) Predicates: Schoelly FSC 50MH K053412
21 CFR 876.1500, Endoscope and accessories, Class II, Product code GCT and FWC
21 CFR 878-4160, Surgical camera and accessories, Class I, 510(k) exempt, product code FWF

D) Device Description: The Schoelly FSC 2 is a camera hand piece with built-in LED illumination intended to be used with Schoelly endoscopes. The light source provides illumination to the area under endoscopic examination. The compact camera component attaches to the proximal eyepiece of the endoscope via the Flexilock connector. Optically captured images are transferred to the camera, converted to an electrical signal, and amplified for output to accessories such as a computer.

E) Intended Use: The FSC 2 is to be used in conjunction with endoscopic devices to provide illumination and video visualization of optical images.

F) Comparison to Predicate Device(s):

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Features	**FSC 2**	**Predicate: K053412 FSC 50 MH/ 50 MHC**
General design	Camera with LED lamp type	Camera with metal halide lamp type
Intended Use	Use in conjunction with endoscopic devices to provide illumination and video visualization of optical images	Use in conjunction with endoscopic devices to provide illumination and video visualization of optical images
Target population	Any patient population	Any patient population
Anatomical sites	Any where endoscopic devices are used	Any where endoscopic devices are used
Where used	Hospitals, clinics, and physician offices	Hospitals, clinics, and physician offices
Biocompatibility	NA – no patient contacting surfaces	NA- no patient contacting surfaces
Sterility	NA – non-sterile	NA - non-sterile
Electrical safety	Conforms with IEC 60601-1	Conforms with IEC 60601-1
Mechanical safety	NA	NA
Performance	NA	NA

G) Standards met:

IEC 60601-1 *Medical Electrical Equipment – Part 1: General Requirements for Safety*

H) Conclusion:

Schoelly Imaging, Inc. believes that the FSC 2 is substantially equivalent to the predicate device based on the same the general design and technology, indication for use, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2009

Schoelly Imaging, Inc.
% Mr. F. David Rothkopf
President
MEDIcept, Inc.
200 Homer Avenue
ASHLAND MA 01721

Re: K090601
Trade/Device Name: FSC 2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NTN
Dated: March 2, 2009
Received: March 5, 2009

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

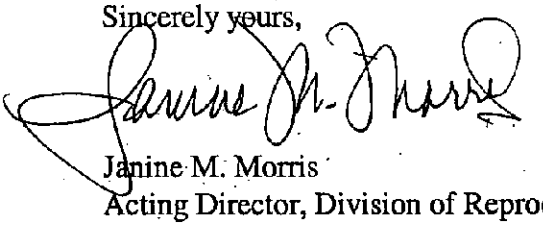
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K090601

Device Name: FSC 2

Indications for Use: The FSC 2 is intended to be used in conjunction with endoscopic devices to provide illumination and video visualization of optical images to visualize and observe body spaces.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device InVitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign Off
Office of Device InVitro Diagnostic Device Evaluation and Safety

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090601

510 (K) _____